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and Dennis Roscetti )
Serial No.: 09/109,119 )

polication of: Benjamin W. Boldt

Examiner: **Jeanine Goldberg** 

Filed: 06/30/98 )
Group Art Unit: 1634 )

For: A Process For Detecting A Known Sequence In Genomic DNA

# AMENDMENT UNDER 37 C.F.R. § 1.111

Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

This Amendment responds to the Office Action dated March 6, 2002. Kindly amend the application as follows:

In the Claims:

Please capicel claims 2, 6 and amend claims 1, 3, 7 and 13 as follows:

A clean version of each replacement claim is submitted below. Please enter each claim.

- 1. (Amended) A process for testing genomic DNA to determine if a targeted base is present, comprising:
  - a. making a solution comprising the genomic DNA;
  - b. adding a primer directed to the targeted base wherein the primer 3' nucleotide will hybridize to the targeted base if the targeted base is present favoring primer extension or the primer 3' nucleotide will not hybridize because the targeted base is not present thereby inhibiting primer extension;
  - c. mixing a DNA polymerase into the solution;
  - d. amplifying a sequence of the genomic DNA containing the targeted base if it is present;
  - e. capturing the amplified sequence to a solid support wherein the solid support contains probes that hybridize to the amplified sequence between the primers; and,
  - f. detecting amplified sequence if the targeted base is present.

E 2 3.

(Amended)
The process of claim 1 further comprising denaturing amplified polynucleotide strands to form single-stranded polynucleotides.

7. The process of

- The process of claim 5 wherein the solid support comprises a microtiter plate.
- 13. (Amended) A process for detecting a targeted base in a sequence of genomic DNA, comprising:
  - a. obtaining the genomic DNA;
  - b. mixing the genomic DNA with a primer that hybridizes to the sequence of the genomic DNA wherein the primer 3' nucleotide hybridizes to the targeted base if the targeted base is present;
  - c. amplifying the sequence of the genomic DNA containing the targeted base if the targeted base is present;
  - d. capturing amplified polynucleotide strands to a solid support wherein the solid support contains probes that hybridize to amplified sequence between the primers; and.
  - e. detecting amplified targeted sequence if the base is present.

#### <u>REMARKS</u>

### Objection to the Specification under 35 U.S.C. 112:

In the Office Action, on page 3, claims 1-16 have been rejected under §112.

Applicants have amended independent claims 1 and 13 to clarify the claims. The term "targeted base" has been added to differentiate between the 3' primer nucleotide and the genomic targeted base.

The rejected term "targeted sequence" has been removed.

Claim 2 has been canceled to remove the objection.

Accordingly, Applicants believe that the §112 rejections are obviated by the amendments.

#### Rejection of claims 1, 2 and 13 under 35 U.S.C. 102:

Claims 1, 2, 13 have been rejected under §102 as being anticipated by Newton et al. Applicants have amended claims 1 and 13 according to the April 17, 2002 telephone conference. Claim 2 has been cancelled.

Applicants' process uses a solid support that contains probes that hybridize to amplified sequence between the primers. In contrast, the Newton et al. reference does not teach the capture of amplified sequence between the primers to a solid support.

Applicants believe that the rejection has been obviated. Therefore independent claims 1 and 13 along with their dependent claims are believed to be allowable.

Claims 1, 2, 13 have been rejected under §102 as being anticipated by Ugozzoli et al. The cited prior art utilized a system where PCR product was first made with non-specific primers and next used with specific primers. This differs from Applicants' process where the specific primers determine whether or not PCR occurs.

Applicants have amended their claims and believe that Ugozzoli et al. does not anticipate their process.

# Rejection of claims 1-16 under 35 U.S.C. 103:

Claims 1-16 have been rejected under §103 as being obvious using Newton et al. and Monforte et al. as references. Applicants have amended the claims as discussed in relation to the §102 rejections. Therefore, the claims are believed to be not obvious when compared with the cited prior art.

The Office Action's objections and rejections are believed to be overcome by this Amendment and Response. In view of Applicants' amendment and discussion, it is submitted that the claims 1, 3-5, and 7-16 should be allowable and Applicants respectfully request an early notice to such effect.

Respectfully submitted,

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